

Bellus Health

Moving closer to Kiacta Phase III data

Bellus has announced that it now expects the event-driven Phase III study for Kiacta in amyloid A (AA) amyloidosis to be completed in 2016, earlier than the previously anticipated target of 2017. A reduction in the time to study data, and potentially for Kiacta to reach the market, is a positive development and we raise our rNPV valuation to C\$40m (vs C\$26m), or C\$0.87/share (including cash, fully diluted). The potential for premium pricing for Kiacta in an orphan indication underscores the investment case.

Year end	Revenue (C\$m)	PBT* (C\$m)	EPS* (C\$)	DPS (C\$)	P/E (x)	Yield (%)
12/11	3.1	(1.7)	(0.19)	0.0	N/A	N/A
12/12	2.3	(3.5)	(0.11)	0.0	N/A	N/A
12/13e	1.7	(3.2)	(0.07)	0.0	N/A	N/A
12/14e	1.3	(3.5)	(0.07)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding intangible amortisation, exceptional items and share-based payments.

Revised timeline enhances financial flexibility

While Bellus has repeatedly reiterated that it had sufficient financial resources to sustain operations through the previously expected Kiacta study data timeline of 2017, the revised guidance of 2016 increases our confidence in Bellus's capability of meeting this target without further funding. It also provides sufficient flexibility, with partner Auvenc Therapeutics, to out-license or monetise the asset without being rushed to accept a less-than-ideal transaction to avoid running out of funds.

Kiacta extends development lead on competition

Kiacta was already the most advanced-stage drug candidate in clinical trials for AA amyloidosis, but the revised completion timeline may help further insulate its commercial prospects from future potential competition, in the event another molecule (such as Prothena's NEOD001) eventually gains approval in this indication.

Valuation: rNPV raised to C\$40m, C\$0.87/share (fd)

We value Bellus using a risk-adjusted net present value (rNPV) model, using a 12.5% cost of capital. Given the shorter timeline to Kiacta study data (2016), we now project that Kiacta will be launched in the US market in Q417 (versus our previous projection of a launch in H218). This reduces the overall discounting effects in our valuation model for the Kiacta asset, and in combination with revised forex assumptions (to account for Canadian dollar depreciation) leads to an increase in our rNPV valuation to C\$40.0m (from C\$26.0m previously). Our per-share valuation is now C\$1.16 (basic) or C\$0.87 (fully diluted), including C\$15.1m net cash (estimated position at 31 December 2013). This represents significant upside to Bellus's EV of C\$3.9m.

Clinical timeline update

Pharma & biotech

17 January 2014

Price **C\$0.40**

Market cap **C\$19m**

C\$0.915/US\$

Net cash (C\$m) estimated at Q413 15.1

Shares in issue 47.4m

Free float 46%

Code BLU

Primary exchange TSX

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs 0.0 19.1 127.3

Rel (local) (4.4) 14.3 99.3

52-week high/low C\$0.46 C\$0.24

Business description

Bellus Health is a Canadian pharmaceutical company developing drugs for rare diseases. Its lead candidate, Kiacta, is in a pivotal Phase III trial for AA amyloidosis. Shigamabs is in preclinical development for Shiga toxin-associated haemolytic uremic syndrome.

Next events

Q413 results February 2014

Completion of enrolment for Kiacta Phase III trial Q214

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Update: Reducing Kiacta's data timeline

On 9 January 2014, Bellus provided an update on the ongoing Phase III study for lead candidate Kiacta (eprodysate), for the treatment of amyloid A (AA) amyloidosis. The study is designed to recruit 230 patients, and to date approximately 200 have been enrolled, with recruitment expected to be completed in Q214. More importantly, as an event-driven study (un-blinding and study analysis between treatment and placebo arms will occur once there have been 120 events across both arms), and with 40 events recorded thus far, Bellus now expects the study to conclude in 2016, earlier than its previous guidance of 2017. The primary endpoint, agreed on by both European and US regulators, is time from baseline to first worse persistent event, with an event defined as a decrease in creatinine clearance (CrCl) of at least 40%, an increase of serum creatinine (SCr) of at least 80%, or progression to end-stage renal disease (ESRD).

The reduced timeline for Kiacta study completion and data is favourable to Bellus for several reasons:

- It shortens the length of time until the product could be partnered and commercialised (if study data are positive), and thereby reduces the discounting of future potential cash flows from the product's commercialisation and/or out-licensing.
- A quicker time-to-market for Kiacta would better insulate the product's commercial prospects from competition in the event that a competing therapeutic eventually gains approval in AA amyloidosis. Kiacta is currently the most advanced-stage drug candidate in clinical trials for AA amyloidosis, but we note that Prothena is evaluating NEOD001 (a monoclonal antibody targeting AL and AA amyloid) in a Phase I trial for AL amyloidosis (data expected in 2014) and may also pursue studies in AA amyloidosis.
- The shorter timeline also reduces Bellus's funding risk. While management has repeatedly reiterated that it had sufficient financial resources to sustain operations through the previously expected Kiacta study data timeline of 2017 (and our model assumed funds on hand were sufficient to maintain operations through Q118), the 2016 study completion target gives us increased confidence in Bellus's capability (without further funding) to meet this goal. It also provides sufficient flexibility afterwards, with partner Auvon Therapeutics, to out-license or monetise the asset without being rushed to accept a less-than-ideal transaction to avoid running out of funds.

Valuation and financials

We value Bellus using a risk-adjusted net present value (rNPV) model, using a 12.5% cost of capital. Our valuation is based on our assessment for the potential for lead candidate Kiacta in AA amyloidosis. We continue to assume Auvon and Bellus will partner Kiacta on obtaining positive Phase III results and that these parties will be collectively entitled to royalties of 25% of net sales, US\$30m in upfront and up to US\$60m in milestone payments (Bellus's net share would reflect a 12.5% royalty and up to US\$45m in upfront and milestones).

Given the earlier timeline to Kiacta study data (2016), we now project that Kiacta will be launched in the US market in Q417 (versus our previous projection of a launch in H218). We continue to assume the initial US treatment cost of Kiacta will be US\$40,000/year (in the lower-to-mid range of products for serious diseases with similar prevalence levels to AA amyloidosis). As an orphan drug, we assume seven years of marketing exclusivity in the US and 10 years in Europe and Japan. We assume Kiacta will receive a peak market share of 30% of AA amyloidosis patients within four years of launch; we define the market as 16,500 patients in the US, up to 24,000 in Europe and 5,000 in Japan.

Bringing forward our Kiacta commercialisation and out-licensing revenue estimates earlier by about three quarters reduces the overall discounting of our rNPV valuation for the Kiacta asset, and is largely responsible for increasing our valuation to C\$40.0m (from C\$26.0m previously). We also note that the depreciation in the Canadian dollar versus the US dollar (current exchange rate of C\$0.915/US\$ versus a previous assumption of C\$0.98/US\$) also raises the rNPV for Kiacta in Canadian dollars (as the majority of future Kiacta sales revenue is expected to come from the US market).

Our C\$40.0m rNPV calculation, or C\$1.16 per share (basic)/C\$0.87 per share (fully diluted) inclusive of C\$15.1m net cash (estimated position at 31 December 2013) represents significant upside to Bellus's EV of C\$3.9m.

Exhibit 1: Bellus Health rNPV assumptions

Product	Status	rNPV (C\$m)	Probability of success	Estimated launch year	Estimated peak US market share	Market value (US\$m)	Estimated max royalty	Estimated peak WW sales (US\$m)
KIACATA (AA amyloidosis)	Phase III	40.0	60%	2017	30%	1,460	12.5%	432 in 2023
Total pipeline rNPV		40.0						

Source: Edison Investment Research

Our fully diluted (FD) share calculation of 65.63m shares is based on 47.43m listed shares outstanding and includes the conversion of the notional C\$10.93m Amended Note (which will convert into 7.29m common shares in 2016), the exercise of 4.57m current options outstanding (exercisable at C\$0.50/share) and the conversion of Pharmascience's 10.4% interest in BHI LP into 6.35m Bellus shares. BHI LP is the entity that holds Bellus's operating assets and IP, and Bellus owns 89.6% of BHI LP. Pharmascience has the right to exchange its BHI LP interest into 6.35m Bellus shares. Bellus can force Pharmascience to exercise this right after September 2016.

Exhibit 2: Financial summary

	C\$000s	2011	2012	2013e	2014e	2015e
Year end 31 December		IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue		3,066	2,298	1,694	1,314	1,264
Cost of Sales		0	0	0	0	0
Gross Profit		3,066	2,298	1,694	1,314	1,264
General & Administrative		(2,357)	(4,961)	(4,029)	(3,867)	(3,944)
Research & Development		(1,315)	(954)	(1,206)	(1,242)	(1,282)
EBITDA		(606)	(3,617)	(3,541)	(3,795)	(3,962)
Operating Profit (before amort. and except.)		(1,792)	(3,617)	(3,541)	(3,799)	(3,971)
Intangible Amortisation		0	0	0	0	0
Exceptionals		5,108	(9,690)	1,831	0	0
Other		0	0	0	0	0
Operating Profit		3,316	(13,307)	(1,710)	(3,799)	(3,971)
Net Interest		108	137	362	269	199
Profit Before Tax (norm)		(1,684)	(3,480)	(3,180)	(3,529)	(3,772)
Profit Before Tax (FRS 3)		3,424	(13,170)	(1,349)	(3,529)	(3,772)
Tax		0	0	0	0	0
Profit After Tax (norm)		(1,684)	(3,480)	(3,180)	(3,529)	(3,772)
Profit After Tax (FRS 3)		3,424	(13,170)	(1,349)	(3,529)	(3,772)
Average Number of Shares Outstanding (m)		8.9	32.3	47.4	48.7	50.8
EPS - normalised (C\$)		(0.19)	(0.11)	(0.07)	(0.07)	(0.07)
EPS - normalised and fully diluted (C\$)		(0.08)	(0.11)	(0.06)	(0.06)	(0.06)
EPS - (IFRS) (C\$)		0.39	(0.41)	(0.03)	(0.07)	(0.07)
Dividend per share (p)		0.0	0.0	0.0	0.0	0.0
BALANCE SHEET						
Fixed Assets		6,275	7,441	6,997	7,033	7,068
Intangible Assets		0	0	0	0	0
Tangible Assets		218	844	1,879	1,915	1,950
Investments (new ABCP Notes)		6,057	6,597	5,118	5,118	5,118
Current Assets		6,043	19,657	16,072	12,672	9,048
Short-term investments		0	7,824	4,653	0	0
Debtors		0	0	0	0	0
Cash		5,105	10,745	10,465	11,490	7,886
Other		938	1,088	953	1,182	1,162
Current Liabilities		(6,372)	(2,679)	(2,836)	(2,836)	(2,836)
Creditors		(6,372)	(2,679)	(2,836)	(2,836)	(2,836)
Short term borrowings		0	0	0	0	0
Long Term Liabilities		(44,768)	(13,343)	(9,923)	(9,209)	(8,495)
Long term borrowings		(40,599)	(8,245)	(5,186)	(5,186)	(5,186)
Other long term liabilities		(4,169)	(5,098)	(4,737)	(4,023)	(3,309)
Net Assets		(38,822)	11,076	10,309	7,660	4,785
CASH FLOW						
Operating Cash Flow		(5,959)	(3,149)	(3,770)	(3,857)	(3,759)
Net Interest		108	137	362	269	199
Tax		0	0	0	0	0
Capex		0	0	(10)	(40)	(44)
Acquisitions/disposals		1,337	8,220	495	0	0
Financing		1	0	0	0	0
Dividends		0	0	0	0	0
Other		0	0	0	0	0
Net Cash Flow		(4,513)	5,208	(2,924)	(3,628)	(3,604)
Opening net debt/(cash)		31,635	29,437	(16,921)	(15,050)	(11,422)
HP finance leases initiated		0	0	0	0	0
Other		6,711	41,150	1,053	0	0
Closing net debt/(cash)		29,437	(16,921)	(15,050)	(11,422)	(7,818)

Source: Bellus Health, Edison Investment Research. Notes: Increases in shares outstanding relate to our assumptions for annual stock-based compensation. In May 2012, Bellus received C\$17.25m from Pharmascience, reflecting C\$8.2m for the disposal of its unrecognised deferred tax loss assets (including c C\$40m in carry-forwards, C\$125m in federal R&D expenses and C\$21m in federal R&D tax credits), and C\$9.1m for 10.4% of BHI LP. Holders of Bellus notes and preferred shares also converted their positions into 40.5m common shares, reducing Bellus's balance sheet liabilities by C\$32.6m and simplifying Bellus's capital structure. Bellus recorded C\$1.3m in related transaction costs as part of its C\$5.0m in FY12 G&A expense. Bellus has a secured revolving credit facility with the chartered bank that sold the ABCP to Bellus, which bears interest at Canadian prime rate minus 1%.

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